

61 AF/1743

Appellant's Brief Under 37 C.F.R. § 1.192
Application No. 09/685,297
Paper Dated November 21, 2003
Reply to USPTO Correspondence of September 9, 2003
Attorney Docket No. 3487-001146



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS AND INTERFERENCES

Application No. : 09/685,287 Confirmation No. 4559
Applicant : ROBERT B. CODY
Filed : October 10, 2000
Title : CHEMICAL ANALYSIS METHOD FOR MULTIPLEXED SAMPLES
Group Art Unit : 1743
Examiner : Brian R. Gordon

APPEAL BRIEF

Mail Stop Appeal Brief - Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Appeal Brief is submitted in support of the Reinstatement of Notice of Appeal mailed concurrently herewith. The Notice of Appeal appeals the final rejection of claims 1-9.

The headings used hereinafter and the subject matter set forth under each heading are in accordance with 37 C.F.R. § 1.192(c).

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 21, 2003.

Lori A. Fratangelo
(Name of Person Making Deposit)
Lori A. Fratangelo 11/21/2003
Signature Date

I

REAL PARTY IN INTEREST

JEOL USA, Inc. is the Assignee of the entire right, title, and interest to the above-identified application and, as such, is the real party in interest in this Appeal.

II

RELATED APPEALS AND INTERFERENCES

There are no other pending appeals or interferences known to the Appellant, the Appellant's legal representative, or the Assignee of the above-identified application which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal. This is the second appeal in this application, the examiner having withdrawn the first appeal from a final rejection based upon prior art, and issued an new final rejection on entirely different grounds (35 U.S.C. §112, first paragraph).

III

STATUS OF CLAIMS

Claims 1-9 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which the invention pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-9 are reproduced in Appendix A which is attached hereto.

IV

STATUS OF AMENDMENTS

A Response after the first final rejection was submitted in this application on September 17, 2002 arguing for the allowability of the claims but making no claim amendments. There were no claim changes made after the Final Office Action dated July 18, 2002 or after the first Office Action on the merits dated January 15, 2002. The claims on

appeal are the claims as originally filed on October 10, 2000, which were finally rejected in the Final Office Action of July 18, 2002 and now in the Final Office Action of September 9, 2003.

V

SUMMARY OF THE INVENTION

The claims on appeal are directed toward a new and nonobvious (as already determined by the prosecution of this application) method for analyzing a plurality of fluid specimens with a single analyzing instrument. The method includes the steps of:

- a) preparing a plurality of N fluid specimens;
- b) introducing a first combination of r specimens wherein r is less than N into a homogenizing volume to create a homogenized specimen;
- c) introducing at least a portion of the homogenized specimen to the analyzing instrument and recording the results of the analysis maintaining an association with the combination of r specimens;
- d) introducing additional different combinations of specimens into said homogenizing volume and repeating steps b) and c); and
- e) with a programmed digital computer mathematically processing the recorded results to produce analyses corresponding to individual fluid specimens.

As discussed in the present specification at pages 1 and 2, a problem with conventional analysis methods of fluid specimens is a poor signal-to-noise ratio for a given time period. In order to deal with this problem, specimens are conventionally measured one at a time, multiple times, in order to gain an acceptable signal-to-noise ratio. Thus, an extremely long period of time for analysis is required in order to have an acceptable signal-to-noise ratio. In Appellant's invention, this problem is overcome by providing a plurality of fluid samples simultaneously and analyzing them using a multiplexed sampling method that

includes a mathematical transform technique to improve the signal-to-noise ratio for a given time period or to shorten the time period for a given signal-to-noise ratio.

VI

ISSUES PRESENTED

Whether an enabling disclosure has been provided for the subject matter of claims 1-9.

VII

GROUPING OF CLAIMS

Claims 1-9 stand or fall together.

VIII

ARGUMENT

The examiner has raised a number of specific questions concerning the appellant's disclosure that will be dealt with one by one.

The examiner notes the absence of "specific working examples". As explained in MPEP § 2164.02: "[c]ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." As explained in a following paragraph of the MPEP: "[t]he specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970)." As will become apparent by the Appellant's response to the examiner's specific questions, those skilled in the art would have no difficulty practicing the Appellant's invention without undue experimentation.

The examiner states: "[t]here are no specifics given as to how the N specimens are 'prepared'".

Mass spectrometry, for example, is a well-established art. The same is true of other instruments that analyze fluid specimens. Samples (specimens) are prepared by well-known methods available to those of ordinary skill in the art. For example, samples are diluted in a solvent that is suitable for the method of introduction to be used and diluted samples are placed in vials or other sample containers for analysis. The samples are then ready for introduction, which may be directly or via a gas or liquid chromatograph. The use of a chromatograph to introduce samples to mass spectrometers is well known as shown in Norman U.S. Patent No. 5,508,204 previously cited by the examiner. There is nothing special or unusual about the preparation of fluid samples for the practice of Appellant's invention.

The examiner states: "Furthermore, there is no reasoning given for 'introducing a first combination of r specimens where r is less than N into a homogenizing volume'. It is unclear why one would want to combine a number of specimens less than N, or any number of specimens to simultaneously analyze the mixture only to deconvolute the results."

The question here is whether the disclosure is enabling. As long as those skilled in the art can practice the claimed process steps without undue experimentation, the disclosure is enabling. The "reasoning" or "why" for a given step is immaterial to the enablement of the step. However, Appellant has set forth the "reasoning" and the "why" as explained under the heading "Background of the Invention". The reasoning for introducing a combination of specimens and then deconvoluting the results is to reduce the signal-to-noise ratio in the results in a shorter period of time. From this follows a higher throughput when analyzing a large number of samples.

The examiner states: "[i]t is unclear how combining the specimens would be an advantage over the prior art when it has already been disclosed the individual specimens

may be analyzed simultaneously.” (Quote from rejection of 3/5/03.) Again, the issue here is enablement not advantages. The advantages over the prior art are unrelated to whether the disclosure enables those skilled in the art to practice the invention without undue experimentation. However, as already explained, the combining of specimens as set forth in Appellant’s claims enables the reduction of the signal-to-noise ratio in the analysis of numerous samples in a shorter period of time. Moreover, the prior art does not disclose “individual specimens may be analyzed simultaneously” using the same instrument. Norman U.S. Patent No. 5,508,204 discloses sequential, not simultaneous analysis. If all samples (specimens) were mixed and fed to an analytical instrument simultaneously, no sample could be analyzed. The advantage of submitting combinations less than all of the samples is to enable deconvolution and thus obtain spectra of all samples with reduced signal-to-noise ratios.

The examiner states: “[t]here is also lack of basis of what is meant by ‘homogenizing’ and the importance of conducting this step. The examiner considers an individual specimen, which contains different elements to be homogenized, and furthermore any mixture is a combination of uniformly distributed substances.”

The examiner may consider that a mixture is a combination of uniformly distributed substances, but in fact (as anyone who has ever added cream to a cup of hot coffee knows), when fluid specimens are first combined, they are not uniformly distributed and, therefore, the Appellant includes the step of introducing the combination of specimens “into a homogenizing volume to create a homogenized specimen.” The specimens become uniformly distributed in the homogenizing volume prior to being introduced into the analytical instrument. The basis of this step is simply to provide a uniform mixture for simultaneous analysis.

The examiner states: "The specification also fails to particularly show a working example in which a programmable digital computer is employed to mathematically process the recorded data." (Quote from rejection of 3/5/03.)

The specification at page 5, line 21 - page 6, line 2, describes the mathematical basis of deconvolution. Programs for performing deconvolution are known to those of ordinary skill in the art. As stated in Appellant's specification, the Hadamard transform method is well known in spectroscopy and is essentially based on solving simultaneous equations in unknowns to deconvolute the stored results. Disclosures are addressed to those of ordinary skill in the art. As stated in MPEP §2164: "[d]etailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention." As stated in MPEP §2164.01: "A patent need not teach, and preferably omits, what is well known in the art." [Emphasis ours.]

The examiner states:

The disclosure also lacks the proper evidence to determine that the method could be performed as claimed to allow one to obtain the results as claimed by applicant. The method suggests that two or more unknown samples are mixed together and then are subjected to analysis that allows one to identify characteristics of the individual samples. However, it is well known in the art that when chemicals are mixed together chemical reactions may occur in which a new chemical is produced or the original samples are altered or entirely consumed in the reaction. Since the originally prepared samples may be altered or consumed, it is unclear how one would analyze the mixed samples and then deconvolute the results to obtain data that would identify or relate to the original samples. This would be particularly difficult or incorrect if the original samples are consumed in the reaction. Since the mixing of the samples may provide for the occurrence of unpredictable chemical reactions, it is unclear how such a method could be accurately executed as claimed by applicant. Therefore, the scope of the disclosure does not provide adequate support for enablement of the objective of the invention which appears to be in contrast of

generally accepted scientific principles of mixing and analyzing chemicals.

The examiner also states:

Applicant does not specify the type of specimens that are mixed so there is no guarantee that the samples will mix to form a homogeneous mixture. Depending the samples, it may be possible for the samples to be combined and produce a solid precipitate.

The examiner is asserting that the invention is "in contrast of generally accepted scientific principles of mixing and analyzing chemicals." However, it is well known that most chemicals do not react with each other instantaneously or at all and, therefore, even based upon known scientific principles, Appellant's claimed invention satisfies the requirements of 35 U.S.C. § 112 in describing a useful method. Moreover, filed in this application is a Declaration Under 37 C.F.R. § 1.132 of the inventor setting forth the results of two experiments, one in which three chemical compounds were analyzed two at a time and then resolved into individual spectra, and another example in which seven chemicals were analyzed four at a time and then resolved into individual spectra. The Declaration establishes that Appellant's method is not contrary to scientific principles. Simply stated, Appellant's method is useful in all situations where those of ordinary skill in the art might choose to apply it. It would not involve undue experimentation to avoid combinations of chemicals that instantly react.

The examiner states: "Claim 2 recites that the specimens are gaseous specimens diluted with a carrier gas. The only mentioning of gas is found in the Background of the Invention on page 1, line 11 and Summary of the Invention on page 2, lines 27-28. However, there is no working example given with which the specific method would be employed." (Quote from rejection of 3/5/03 and final rejection of 9/9/03.)

As pointed out above, a specific working example is not required to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, so long as those skilled in the art

can practice the invention claimed without undue experimentation. There is no reason to believe that gaseous specimens would be more difficult to use than other fluid specimens.

Again, the rejection here is enablement under 35 U.S.C. § 112, first paragraph. Whether an invention is beneficial (or useful implicating 35 U.S.C. § 101) or whether the invention is enabled are two different questions. But, as set forth above, the reason the invention is beneficial is that the signal-to-noise ratio of the obtained spectra can be reduced in a shorter period of time. In any event, the § 1.132 Declaration submitted clearly establishes that the invention is useful.

MPEP 2017:

Once a *prima facie* showing of no specific and substantial credible utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR 1.132 or a patent or a printed publication that rebuts the basis or logic of the *prima facie* showing. If the applicant responds to the *prima facie* rejection, the Office personnel should review the original disclosure, any evidence relied upon in establishing the *prima facie* showing, any claim amendments, and any new reasoning or evidence provided by the applicant in support of an asserted specific and substantial credible utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained.

The examiner states:

It appears that applicant has taken well known methods and principles (as admitted by applicant) to produce a method in which applicant now recites that multiple samples are combined. However due to the lack of working examples and evidence of how such a method would be beneficial the examiner hereby asserts that the specification is not enabled for the claimed method. [Emphasis added.]

The examiner's acknowledgement that the Appellant has used well-known methods and principles in the implementation of his particular methods (which have already been established to be new and nonobvious satisfying the provisions of 35 U.S.C. §§ 102 and 103), is, in fact, an acknowledgment that those of ordinary skill in the art can practice the claimed method without undue experimentation and, therefore, the enablement requirement of 35 U.S.C. § 112, first paragraph, is satisfied by the Appellant's specification.

Again, the rejection here is enablement under 35 U.S.C. § 112, first paragraph. Whether an invention is beneficial (or useful implicating 35 U.S.C. § 101) or whether the invention is enabled are two different questions. But, as set forth above, the reason the invention is beneficial is that the signal-to-noise ratio of the obtained spectra can be improved for all specimens in a shorter period of time. It is beyond question that the Appellant's specification discloses a specific and substantial utility. At page 6 of the specification, the Appellant explains the theoretical improvement in signal-to-noise ratios resulting from multiple trials simultaneously conducted.

Moreover, the § 1.132 Declaration submitted clearly establishes that the invention is useful in removing background noise from the mass spectra of the plural specimens.

IX

SUMMARY

The claims define a unique method for analyzing a plurality of fluid specimens with a single analyzing instrument. The specification teaches one skilled in the art how to practice the invention with little or no experimentation. The specification discloses all the advantages, utility, and reasons necessary to satisfy the requirement of 35 U.S.C. § 112, first paragraph. If that were not sufficient, the § 1.132 Declaration filed herein discloses that the specific and substantial utility disclosed in the specification is real.

X

CONCLUSION

Reversal of all of the examiner's rejections and allowance claims 1 to 9 is respectfully requested.

A check in the amount of \$320.00 accompanied the prior Appeal Brief after which the final rejection was withdrawn. Hence, no fee is required with this Brief. MPEP §1208.02 The Commissioner for Patents is hereby authorized to charge any additional fees which may be required to Deposit Account No. 23-0650. Please refund any overpayments to Deposit Account No. 23-0650. An original and two copies of this Appeal Brief are enclosed.

Respectfully submitted,

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APPENDIX A
PENDING CLAIMS

1. A method for analyzing a plurality of fluid specimens with a single analyzing instrument comprising the steps for:
 - a) preparing a plurality of N fluid specimens;
 - b) introducing a first combination of r specimens wherein r is less than N into a homogenizing volume to create a homogenized specimen;
 - c) introducing at least a portion of the homogenized specimen to the analyzing instrument and recording the results of the analysis maintaining an association with the combination of r specimens;
 - d) introducing additional different combinations of specimens into said homogenizing volume and repeating steps b) and c); and
 - e) with a programmed digital computer mathematically processing the recorded results to produce analyses corresponding to individual fluid specimens.
2. The method according to claim 1, wherein the fluid specimens are gaseous specimens diluted with a carrier gas.
3. The method according to claim 2, wherein the analyzing instrument is a mass spectrometer.
4. The method according to claim 3, wherein the mathematical processing comprises deconvolution.

5. The method according to claim 4, wherein the mathematical processing comprises a Hadamard transform.

6. The method according to claim 1, wherein each specimen is directed into the homogenizing volume from individual nozzles connected to electronically controlled valves.

7. The method according to claim 6, wherein the nozzle sizes, pressure drops therethrough, and open times of said valves is controlled to introduce a specified mass of each fluid specimen into the homogenizing volume.

8. The method according to claim 7, wherein when the nozzles are not supplying specimen to the homogenizing volume the flow of the specimen is diverted and continued.

9. The method according to claim 1, wherein N is an odd number greater than 2 and r is an even number equal to $(N+1)/2$.